

**REMARKS****I. Claim Amendments**

Claims 1 and 2 directed to a copolymer and claims 23-25 directed to a process for making the same have been canceled without prejudice. Applicants reserve the right to resume prosecution of the canceled subject matter in a continuation application.

Claims 3, 4, 7 and 8 have been amended to clarify the polymerization conditions for the recited copolymer and claimed aqueous polymer dispersion. Specifically, claims 3 and 4 have been amended to recite that the emulsifying agent is partially or fully removed after the polymerization reaction. Claims 7 and 8 have been amended to recite that the mixture of monomers to be polymerized in water consists of the three (3) expressly recited monomers.

Claims 27-32 have been amended to depend on any one of claims 4, 6 or 8 directed to the claimed aqueous polymer dispersion.

No new matter has been introduced by any of the claim amendments.

**II. Allowable Subject Matter**

Applicants are appreciative of the indication that claims 5 and 6 represent allowable subject matter. In this regard, the Examiner's attention is directed to page 3 of the Office action where it is stated that claims 5 and 6 "are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims". Claims 5 and 6 are independent claims. Therefore, the objection appears to have been made in error. Withdrawal of the objection is requested.

**III. Claim Rejections – 35 U.S.C. §102**

Claims 1-4, 7, 8, 23, 24 and 31 are rejected under 35 U.S.C. §102(b) as being anticipated by US 4,056,497 to Reinecke et al. ("Reinecke"). In view of the claim amendments, the §102 is moot as to canceled claims 1, 2, 23 and 24.

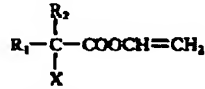
Reinecke discloses crosslinkable and crosslinked acrylic ester copolymers prepared from the following mixture of monomers:

- a. 60 to 95% by weight, calculated on the monomer mixture, of at least one acrylic acid ester and/or methacrylic acid ester of a saturated aliphatic alcohol having from 1 to 20 carbon atoms,

USSN 10/511,115 filed 23 June 2005  
 Atty. Docket No. 1103326-0781  
 Page 8 of 12

b. 0 to 40% by weight, calculated on the monomer mixture, of monomers the homopolymers of which have second order transition temperature of from -40°C to +150°C,

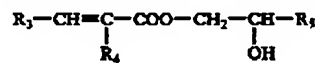
c. 0.1 to 10% by weight, calculated on the monomer mixture, of an  $\alpha$ -haloalkane carboxylic acid vinyl ester of the formula (I)



wherein  $R_1$  and  $R_2$  each represents hydrogen or an alkyl radical having from 1 to 5 carbon atoms and X is fluorine, chlorine, bromine or iodine,

d. 0.1 to 10% by weight, calculated on the monomer mixture of,  $\alpha,\beta$ -ethylenically unsaturated carboxylic acids having from 3 to 8 carbon atoms or their partial ester with saturated aliphatic alcohols having from 1 to 20 carbon atoms and

e. 0 to 10% by weight, calculated on the monomer mixture, of monomers containing hydroxyl groups and having the formula (II)



wherein  $R_3$  is hydrogen, a methyl group or the group --COOR<sub>6</sub>,  $R_4$  and  $R_5$  each is hydrogen or a methyl group and  $R_6$  is hydrogen or an alkyl group having from 1 to 12 carbon atoms.

(col. 1, line 57, to col. 2, line 32)

An aqueous dispersion of the mixture is prepared by free radical polymerization using emulsifiers, protective colloids and, optionally, regulators (col. 3, lines 12-17).

Anticipation requires that each and every feature of the claimed invention be found in a single reference. For the following reasons, Reinecke fails as an anticipatory reference.

a. claims 3-4 and 31/4

Each of these claims requires that the emulsifying agent be partially or fully removed after the polymerization reaction. Reinecke discloses that the prior art aqueous dispersion is prepared by free radical polymerization using emulsifiers, protective colloids and, optionally,

regulators. However, Reinecke does not disclose, either expressly or inherently, that the emulsifying agent is partially or fully removed after polymerization.

As noted in [0050] of the published patent application US 2005/0256255, the presence of residual emulsifier causes instability of the film coat prepared from the dispersion leads to deterioration of the release properties of the coated drug on storage. The partial or complete removal of the emulsifier after polymerization is an expressly recited feature of the claimed invention which is not disclosed by Reinecke. Therefore, Reinecke fails as an anticipatory reference.

Withdrawal of the §102 as to claims 3-4 and 31/4 is requested.

b. claims 7-8 and 31/8

Claims 7 and 8 have been amended to recite that the mixture of monomers to be polymerized in water consists of the three (3) expressly recited monomers: acrylic acid or an ester thereof in the range 40 to 80 % by weight; methacrylic acid or an ester thereof in the range 20 to 60 % by weight; and a polymerizable surfactant in the range 0.01 to 9 % by weight.

In contrast to claims 7 and 8, Reinecke discloses an aqueous copolymer dispersion containing the activated halogen compound (c) and the  $\alpha,\beta$ -ethylenically unsaturated carboxylic acids (d) are examples of such reactive monomers. Each of reactive monomers (c) and (d) must be present in an amount 0.1-10% by weight. By definition, claims 7 and 8 exclude monomers (c) nor (d). Therefore, Reinecke fails as an anticipatory reference.

Withdrawal of the §102 as to claims 7-8 and 31/8 is requested.

IV. Claim Rejections – 35 U.S.C. §103

a. claims 9-14 and 25

Claims 9-14 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in view of US 5,055,306 to Barry et al. ("Barry"). In view of the claim amendments, the §103 is moot as to canceled claim 25.

Barry is directed to a sustained-release formulation in the form of effervescent or water-dispersible tablets (col. 1, lines 5-7). In the paragraph bridging columns 4 and 5, it is stated that "sustained-release formulations of pharmacologically active substances have not previously been

presented, or at least successfully presented, in the form of effervescent or water-dispersible tablets". To solve this problem, Barry discloses a specific coating covering substantially the whole surface of a core containing granules of a pharmaceutically active and effervescent or water-dispersible ingredients. As disclosed at column 3, lines 48-53, the coating comprises the following: 100 parts of a water insoluble but water swellable acrylic polymer, and from 20 to 70 parts of a water soluble hydroxylated cellulose derivative.

The Examiner alleges that it would have been obvious at the time the claimed invention was made to replace the coating disclosed by Barry with one comprised of the acrylic ester copolymer disclosed by Reinecke to arrive at the claimed invention.

Each of the rejected claims 9-14 is dependent, either directly or indirectly, on claims 3-8 directed to an aqueous polymer dispersion. It has been established in the preceding Section III, above, that Reinecke does not anticipate the claimed aqueous polymer dispersion of claims 3-8. In fact, claims 5-6 have already been acknowledged as being directed to allowable subject matter. Barry does nothing to overcome the deficiencies of Reinecke as discussed in Section III, above. Therefore, it is submitted that neither Reinecke nor Barry, whether taken alone or in combination, suggests the pharmaceutical formulation of claims 9-14 which include the limitations of claims 3-8 from which they depend.

Withdrawal of the §103 rejection of claims 9-14 is requested.

b. claims 15 and 16

Claims 15 and 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in combination with Barry, US 5,939,578 to Chen ("Chen") and US 4,957,745 to Jonsson et al. ("Jonsson").

Claims 15 and 16 are directed to the active ingredients of the claimed pharmaceutical formulation. The Examiner notes that Barry does not teach the beta-blocking adrenergic agent to be metoprolol salts such as tartrate, succinate, fumarate or benzoate salt. For this purpose, the Examiner relies on Chen and Jonsson.

Applicants submit that neither Chen nor Jonsson overcomes the failure of the combination of Reinecke and Barry to render the claimed formulation obvious for the reasons given in the preceding Section IV(a).

Withdrawal of the §103 rejection of claims 15 and 16 is requested.

USSN 10/511,115 filed 23 June 2005  
Atty. Docket No. 1103326-0781  
Page 11 of 12

c. claims 27-30 and 32

Claims 27-30 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in combination with US 6,646,046 to Contrada et al. ("Contrada") as further evidenced by GB 1 141 165 ("Zellstoffwerke").

With respect to the limitations of dependent claims 27-30 and 32, the Examiner acknowledges that Reinecke does not teach the repeating units in component (c), i.e., Formula II, and an alkoxy group with C1-20 for the terminal group. For this purpose, the Examiner relies on Contrada and Zellstoffwerke.

Contrada is directed to an aqueous pressure-sensitive adhesive composition. The Examiner relies specifically on the disclosure of the monomer M<sub>1</sub> disclosed at column 3, lines 38-54. Zellstoffwerke is directed to the manufacture of acrylic films. The Examiner relies on the disclosure by Zellstoffwerke of an ester of a polyethoxylated product containing at least one acrylic or methacrylic ester group. The Examiner alleges that the cited compounds of Contrada and Zellstoffwerke, respectively, encompass component (e) of Reinecke.

Each of claims 27-30 and 32 is directly dependent on claim 4, 6 or 8 directed to an aqueous polymer dispersion. It has been established in the preceding Section III, above, that Reinecke does not anticipate the claimed aqueous polymer dispersion of claims 4, 6 and 8. In fact, claim 6 has already been acknowledged as being directed to allowable subject matter. The Examiner's reliance on Contrada and Zellstoffwerke fails to overcome the deficiencies of Reinecke. Therefore, it is submitted that the combination of Reinecke, Contrada and Zellstoffwerke does not suggest the aqueous polymer dispersion of claims 27-30 and 32 which include the limitations of claim 4, 6 or 8 from which they depend.

USSN 10/511,115 filed 23 June 2005  
Atty. Docket No. 1103326-0781  
Page 12 of 12

**V. Conclusion**

In view of the claim amendments and remarks herein, the application is in condition for allowance.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,



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**Attachment:**

- PTO/SB/30 – Request for Continued Examination (RCE) Transmittal (1 page)